

on the replacement pages and not original claims 1 to 15.

Respectfully submitted,
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CAM:sd

Enclosure: Return Receipt Postcard



Marked up version of claims

CLAIMS

1. ^{Step} Process for the processing of information used for the management of quality in a therapeutic process, ~~this~~
 5 ~~therapeutic process~~ comprising the ^{steps} ~~operations~~ of taking cells (PR) from a patient (PA), specific treatment operations on these cells using a specific treatment protocol, and a reinjection operation into the patient of said cells ^{so} ~~treated~~
 10 ~~in this way~~, the ^{steps} ~~operations~~ of taking cells, treatment and reinjection being subjected to a standard operating procedure for preparation (SOP) comprising a series of functional ^{steps} ~~stages~~,
~~characterized in that it comprises~~, for each batch of samples taken from a given patient:
 15 - for each functional ^{step} ~~stage~~, a ^{step} ~~stage~~ of sequential and conditional validation (VA) ^{by processing of data collected} ~~of said stage~~, the passing from one validation ^{step} ~~stage~~ to the following validation stage being conditional on the results of the processing of data collected during this ^{step} ~~stage~~ validation ^{step} ~~stage~~, and
 20 - a ^{step} ~~stage~~ of processing of the ~~information and data collected~~ in the different validation ^{steps} ~~stages~~, ~~in order to issue final certification (CF) of a preparation carried out according to the standard operating procedure and/or a list of the anomalies detected during this preparation.~~
 25 ^{The} 2. ~~Process~~ according to claim 1, ~~characterized in that~~ ^{wherein} validation of the final certification is conditional on the input of a validation password ^{into a computer}
 30 ^{The} 3. ~~Process~~ according to ~~claims 1 and 2~~ ^{wherein} ~~implemented in a data processing system, characterized in that~~ with each validation stage is associated at least one screen page (~~PE~~, ~~PE1~~, ~~EP~~, ~~EA~~, ~~EE~~, ~~E4~~) which can be accessed on ^a ~~the~~ display means of at least one workstation connected to said data
 35 processing system. ^{computer}

- ^{The} 4. ~~Process~~ according to claim 3. ~~characterized in that each~~ ^{wherein}

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screen page comprises a coded identification field for a patient which matches ~~the~~^{or} batch of samples subjected to the standard operating procedure.

- 5 ^{The p} 5.1 Process according to ^{claim 1} ~~any one of the previous claims,~~
~~characterized in that~~^{when} the exit from certain stages (RA) of
said process is conditional on printing the screen pages (EA)
corresponding to these stages.
- 10 ^{The} 6.1 Process according to ^{claim 1} ~~any one of the previous claims,~~
implemented in a preparation laboratory receiving therapeutic
kits from at least one operational entity (EX), ~~characterized~~^{when}
~~in that~~ it further comprises stages for monitoring the
transfer of these kits.
- 15 ^{The} 7.1 Process according to ^{claim 1} ~~any one of the previous claims,~~
implemented in a preparation laboratory which deals with a
cytapheresis service, ~~characterized in that~~^{when} it further
comprises stages for monitoring the receipt of cytapheresis
20 pouches.
- ^{The} 8.1 Process according to ^{claim 1} ~~any one of the previous claims,~~
implemented in a preparation laboratory which deals with a
control laboratory, ~~in particular a bacteriological control~~^{when}
25 ~~laboratory, characterized in that~~ it further comprises stages
for processing the results of control tests carried out on
each batch of samples.
- 30 9. A system for the processing of information used for the
management of quality in a therapeutic process, ^{of claim 1} ~~the~~
~~therapeutic process comprising the operations of taking cells~~
~~(PR) from a patient (PA), specific treatment operations on~~
~~these cells using a specific treatment protocol (SOP), and a~~
~~reinjection operation (RI) into the patient of said cells~~
35 ~~treated in this way, these operations of taking cells,~~
~~treatment and reinjection being subjected to a standard~~
~~operating procedure for preparation comprising a series of~~

functional stages (FR),
characterized in that ^{comprising} it comprises, for each batch of samples
taken from a given patient:

- for each functional ^{stage} stage, a means of sequential and
- 5 conditional validation (VA) of said ^{step} stage, the passing from
one validation ^{step} stage to the following validation ^{step} stage being
conditional on the results of the processing of data
collected during this validation ^{step} stage, and
- a means of processing of the ~~information~~ and data collected
- 10 in the different validation ^{steps} stages, ~~in order~~ to issue final
certification (CF) of a preparation carried out according to
the standard operating procedure and/or a list of the
anomalies detected during the preparation.

- 15 10. ^{A_s} system according to claim 9, implemented in a preparation
laboratory, ^{wherein} characterized in that it is further designed to
execute management tasks ~~(GM)~~ within this laboratory.

- 20 11. ^{A_s} system according to claim 9, ^{wherein} characterized in that it is
connected to a communications network in order to exchange
data with other entities ~~(GTA, LD, CYN, GRD, GB)~~ involved in
a therapeutic process. (C)

- 25 12. Application of the process and of the information
processing system used for quality management according to
~~any one of the previous claims~~ ^{claim} to cell therapy protocols.

- 30 13. Application of the process and of the information
processing system used for quality management according to
~~any one of the previous claims~~ ^{claim} to gene therapy protocols.

- 35 14. Application of the process and of the quality management
system according to ~~any one of the previous claims~~ ^{claim}, allowing
ongoing training of the operator and/or the monitoring of his
or her level of knowledge.